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10/599,487	09/29/2006	Seiji Yamamoto	051223-110922	9685

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EXAMINER	
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ART UNIT	PAPER NUMBER
3737	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,487	YAMAMOTO ET AL.	
	Examiner	Art Unit	
	JOSEPH SANTOS	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _09 September 2009_.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _1-11_ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _1-11_ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Abstract

1. The abstract of the disclosure is objected to because the abstract exceeds 150 words in length. See MPEP § 608.01(b).

Correction is required

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim **11** is rejected under 35 U.S.C. 101 because the computer readable medium (CRM) is a generic term that can be directed to a signal and the claim is therefore not statutory. A claim to a generic computer readable medium that, under the broadest reasonable interpretation, can be a CD or a signal, covers a non-statutory embodiment and therefore is non-statutory.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims **1-11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Grimson et al. (US 5,999,840), in view of Shahidi (US 2001/0016684).

As per claim 1, Grimson et al. teach a first acquisition means that optically measures a surface of an operation site during surgery and that acquires first position information representing a three-dimensional position of each of points on the surface of the operation site (Fig. 1 element 116 and Column 5, lines 38-42. Grimson et al., further teaches a second acquisition means that measures a portion of the operation site (Fig 1, element 106 and Column 4, lines 52-57) with ultrasonic waves (Column 5, lines 29-37) during surgery and that acquires second position information representing a three-dimensional position of each of points in the portion of the operation site (Column 5, lines 22-24). Grimson et al., further disclose correction means that, based on the first position information acquired by said first acquisition means and the second position information acquired by said second acquisition means, estimates displacement and distortion at each of the points in the operation site using a three-dimensional model generated based on a plurality of high-definition tomographic images (Column 3, lines 24-27) of the operation site, which images are taken before surgery (Column3, line 50) and that corrects the plurality of high-definition tomographic images. Grimson et al., further teaches a display control means that allows the high-definition tomographic images corrected by said correction means to be shown on display means (Fig. 1 element 126 and Column 7, lines 50-53).

As per claim 2, Grimson et al. further teach a first means for acquisition (Fig.1 element 116) which could be the same mean as laser camera 110 (Column 5, lines 40-43). **Error! Reference source not found.** further teaches element 110

scan the surface of the operation site with laser light, and detecting means and receiving laser light reflected by the surface of the operation site, thereby detecting a three-dimensional position of a portion on which the laser light is irradiated, on the surface of the operation site, and an operation of detecting the three-dimensional position by said detecting means is carried out repeatedly while scanning each of the points on the surface of the operation site with laser light, thereby acquiring the first position information.

As per claim 3, Grimson et al. further teach said first acquisition means (Fig 1. element 116) further comprises image pickup means producing images of the surface of the operation site (Column 5, lines 16-24), and said correction means is provided so as to estimate displacement and distortion at each of the points in the operation site also using images produced by said image pickup means.

As per claim 4, Grimson et al. further teach the limitations of said second acquisition means (Fig 1, element 106) comprises a probe (Fig 1, element 110) that transmits ultrasonic waves to the operation site and receives ultrasonic waves reflected by the points in the portion of the operation site, and conversion means that converts the ultrasonic waves received by the probe to tomographic images, and said second acquisition means is provided so as to acquire the second position information by obtaining the three-dimensional position of each of the points on the ultrasonic tomographic images obtained by said conversion means (Column 5, lines 29-36). Grimson et al. disclose the element 116 could be the same as laser scanning unit 110 (Column 5, lines 40-42) which the laser scanning unit.

As per claim 5, Grimson et al. further teach a said first acquisition means comprises a scanning device (Fig 1, element 116), and scanning the surface of the operation site with laser light and detecting means and receiving laser light reflected by the surface of the operation site, thereby detecting a three-dimensional position of a portion on which the laser light is irradiated, on the surface of the operation site (Column 5, lines 40-43) and (Column 5, lines 16-24)

Grimson et al. teaches said first acquisition means also detects the three-dimensional position of the probe of said second acquisition means; and said second acquisition means obtains, based on the three-dimensional position of the probe detected by said first acquisition means, the three-dimensional position of each of the points on the ultrasonic tomographic image (Column 4, lines 33-35) (Column 5, lines 40-42) and (Column 4, lines 3-6).

As per claim 6, Grimson et al. further teach the limitations of the high-definition tomographic image are an MRI image produced by nuclear magnetic resonance-computed tomography (Column 3, lines 24-27).

As per claim 7, Grimson et al. further teach the limitations of said correction means corrects, based on the first position information acquired by said first acquisition means and the second position information acquired by said acquisition means, a position of a portion whose three-dimensional position is known by the first position information and the second position information in the three-dimensional model of the operation site, and thereafter, estimates displacement and distortion at a portion whose three-dimensional position is not known in the three-dimensional model of the operation site, by means of a finite element method or a method similar thereto, and based on the estimated result, re-corrects the three-dimensional model of the operation site, and further based on the re-corrected three-dimensional model of the operation site, carries out correction of the plurality of high-definition tomographic images.

Grimson et al., teach a correction transformation that include data points from the imaging means 1 (element 116) and 2 (element 106) in which they are register with one another (Column 8, lines 52-60). The output of this registration is applied to all the data in the transformation stage 213 (Column 10, lines 17-20) and the final stage of the process the transformation has brought the model into alignment with the actual position takes as input a transformed model of the patient's anatomy in which the transformation step has brought the model into alignment with the actual position of the patient in the laser coordinate frame and video view of the patient taken from the laser camera 110. (Column 10, lines 30-

35). In addition, after the 3D model is updated the invention of Grimson et al., teaches the extension of the system which include the re-registration of the video image of the patient to the 3D tomographic image as the patient moves, this way Grimson teaches a cycle comprising the steps of registration of the images, then the updating of the model, following by a re-registration of the images.

As per claim 8, Grimson et al. further teach wherein when the plurality of high-definition tomographic images are produced before a surgical operation, at least three first marks are applied on the periphery of the operation site, and at the time of the surgical operation, at least three second marks are applied to the vicinities of the operation site; said first acquisition means further acquires mark position information that represents respective three-dimensional positions of the first marks and the second marks; said correction means carries out, based on the mark position information acquired by said first acquisition means, and positions of image portions corresponding to the first marks on the high-definition tomographic image, alignment of the high-definition tomographic image and the first position information and the second position information (Column 3 line 65 to column 4 line 11) visualizations of the patient in the operating room (Column 1, lines 61-64).

As per claim 9, Grimson et al. further teach the limitations of operation of acquiring the first position information by said first acquisition means, acquiring the second position information by said second acquisition means, correcting the plurality of high-definition tomographic images by said correction means, and displaying the high-definition tomographic images by said display means is carried out repeatedly during the surgical operation (Column 2, lines 42-45).

As per claim 10, further teach the limitations of a first step in which based on a plurality of high-definition tomographic images of an operation site taken as an image before surgery: a three-dimensional model of the operation site is generated (Column 3, lines 46-48). In addition, a second step in which a surface of the operation site is optically measured during surgery, so as to acquire first position information that represents a three-dimensional position of each of

points on the surface of the operation site, (Fig.1 element 116 and Column 5, lines 38-42) and a portion of the operation site (Fig.1, element 106 and Column 4, lines 52-57) is measured with ultrasonic waves during surgery (Column 5, lines 29-37), so as to acquire second position information that represents a three-dimensional position of each of points of the portion in the operation site ((Column 5, lines 22-24). Grimson et al., further teach a third step in which based on the first position information and the second position information acquired by said second step, displacement and distortion at each of the points in the operation site are estimated using the three-dimensional model generated by said first step, and in accordance with the estimated displacement and distortion at each of the points in the operation site, the plurality of high-definition tomographic images of the operation site taken as images before surgery are corrected (Column 8, lines 52-60), (Column 10, lines 17-20) and (Column 10, lines 30-35). Finally, Grimson et al., further teaches a fourth step in which the high-definition tomographic images corrected by said third step are shown on display means (Fig. 1 element 126 and Column 7, lines 50-53).

As per claim 11, Grimson et al. teach an image data processor (Fig 1. element 118) is an IBM RS6000 or IBM PVS in conjunction with a Sun Sparc 10 (Column 5, lines 48-50). , Grimson et al., shows that the image processor unit 118 is an equivalent structure known in the art. Therefore, because these two elements with embedded programs were art recognized equivalents at the time of the invention was made; one of ordinary skill in the art would have found it obvious to substitute the image processor unit with an embedded program for a “surgical operation program that causes a computer”.

Grimson et al does not teach that the second acquisition means measure an unexposed portion (within the brain) of the operation site. Grimson et al. further fail to teach the laser unit is mounted on a surgical probe.

Shahidi, in the same field of endeavor, teaches a surgical navigation system has a computer with a memory and display connected to a surgical instrument or pointer and position tracking system, so that the location and orientation of the pointer are tracked in real time and conveyed to the computer. The computer memory is loaded with data from an MRI, CT, or other volumetric scan of a patient, and this data is utilized to dynamically display 3-dimensional perspective images in real time of the patient's anatomy from the viewpoint of the pointer. The images are segmented and displayed in color to highlight selected anatomical features and to allow the viewer to see beyond obscuring surfaces and structures. The displayed image tracks the movement of the instrument during surgical procedures. The instrument may include an imaging device such as an endoscope or ultrasound transducer (See Fig. 1), and the system displays also the image for this device from the same viewpoint, and enables the two images to be fused so that a combined image is displayed. The system is adapted for easy and convenient operating room use during surgical procedures. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to expand the invention of Grimson et al. to model and register images acquired within the brain with pre-acquired three dimensional tomographic images in order to further enhanced surgical practices inside the brain by providing real time updates of the brain structures. In addition, it would have been obvious to attach the laser unit in a mounted surgical probe to be able to acquired images inside the brain, as shown by Shahidi.

Response to Arguments

5. Applicant's arguments filed 09/09/2009 have been fully considered but they are moot in view of the new ground(s) of rejection. The changes made to claim 11 were not the same scope as the proposed amendment in the interview conducted on August 18, 2009.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSEPH SANTOS whose telephone number is 571-270-7782. The examiner can normally be reached on Monday through Thursday 7:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, THU NGUYEN can be reached on 571-272-6967. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.S./
Examiner, Art Unit 4155

/Ruth S. Smith/
Primary Examiner, Art Unit 3737